IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

COOPER KIOUS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIV-16-990-R**
	)	
	)	
TEVA PHARMACEUTICALS USA, INC., and PFIZER, INC.,	)	
	)	
	)	
Defendants.	)	

ORDER

This matter comes before the Court on the Motion to Dismiss (Doc. No. 22), filed by Defendant Teva Pharmaceuticals USA, Inc. Plaintiff responded in opposition to the motion. Having considered the parties' submissions, the Court finds as follows.

Plaintiff filed this action in the District Court of Oklahoma County alleging that Defendant Teva, which manufactures azithromycin, a generic form of the antibiotic Zithromax, is liable to him for injuries he sustained when he developed Stevens-Johnson Syndrome after ingesting the drug. His claims, premised on state law, include strict liability design defect, failure to warn, negligence, breach of warranties, fraud, negligent misrepresentation, and fraudulent concealment. Defendant asserts that the essence of each of Plaintiff's claims is a contention that the warnings given by Defendant Teva were inadequate. *See e.g.* Amended Petition, ¶ 18, 19, 20, 21, 29, 40, 43. As a result, Defendant contends Plaintiff's claims against it are preempted on the basis of impossibility, because it could not both comply with state law and the Federal Food, Drug, and Cosmetic Act

("FDCA"), 21 U.S.C. § 301 *et seq.* Defendant alternatively contends Plaintiff has failed to state a claim based on federal pleading standards. Plaintiff contends he has sufficiently pled his claims and that his claims are not preempted.

Pursuant to the Supremacy Clause of the United States Constitution, federal law is "the supreme Law of the Land" notwithstanding any state laws to the contrary. U.S. Const. art. IV, cl. 2. "Accordingly, it has long been settled that state laws that conflict with federal law are without effect." *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2471 (2013) (quotation omitted). Accordingly, if "it is impossible for a private party to comply with both state and federal [law]," the state law is preempted. *Id.* (quotation omitted). Federal preemption is an affirmative defense upon which the defendants bear the burden of proof. *Wyeth v. Levine,* 555 U.S. 555, 573, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009).

As a result of the 1984 Hatch-Waxman amendments to the FDCA, and its attendant regulations, generic drugs, such as the azithromycin at issue herein, may be approved for sale by the FDA via swifter route. *Mutual Pharmaceutical Co., Inc. v. Bartlett*, --- U.S. ---, 133 S.Ct. 2466 (2013). Prior to that time all manufacturers seeking approval to market a new drug were required to "prove that it is safe and effective and that the proposed label is accurate and adequate." *PLIVA, Inc. v. Mensing*, —— U.S. ——, 131 S.Ct. 2567, 2574, 180 L.Ed.2d 580 (2011) (citing 21 U.S.C. § 355(b)(1), (d)). The amendments, however, permitted the marketing of a generic version of a reference listed drug provided it is equivalent to the reference listed drug that has undergone the process for FDA approval. These drugs, which are approved via an abbreviated new drug application, as known as ANDAs, or more commonly, as generic drugs. Hatch-Waxman permitted approval of

ANDAs without the same rigorous level of testing required for new brand-name drugs, provided that the ANDA has the same active ingredients, method of administration, dosage form, and strength as the brand-name drug, and the labels, to include warnings, must be identical to those of the brand-name drug. *Mensing*, 131 S.Ct. at 2574 & n. 2; 21 U.S.C. § 355(j)(2)(A)(ii)-(v). Once the ANDA receives FDA approval, its manufacturer is prohibited from changing its formulary or its labeling. *See Bartlett*, 133 S.Ct. at 24 71. With this background in mind, the Court turns to Plaintiff's specific claims.

Citing *Mutual Pharm. Co. v. Bartlett*, 570 U.S. ---, 133 S.Ct. 2466 (2013), Defendant contends that Plaintiff's design defect claims are preempted by federal law. In *Bartlett*, the lower court held that design-defect claims against the manufacturer of generic drugs were not preempted by *Mensing*, because the manufacturer could simply choose to withdraw the medication from the market, thereby complying with both state and federal law. *Id.* at 2470. The Supreme Court rejected this conclusion, explaining that generic-drug manufacturers are legally required to conform the composition of their drug to the composition of the brand name drug. The Supreme Court held that design defect claims based on state law would "place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling." *Id.* at 2479. This, however, could be "in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id.* Furthermore, a generic manufacturer is not obligated to leave the market when it is incapable of complying with both federal and state obligations; because such a choice would render impossibility preemption "all but meaningless." *Id.* at 2477 (quoting *Mensing*, 131 S.Ct. at 2579).

The Tenth Circuit Court of Appeals in *Schrock v. Wyeth, Inc.*, 727 F.3d 1273 (10th Cir. 2013), noted that *Bartlett* applies design defect claims.

> Further, the [Bartlett] Court extended its reasoning in *Mensing* to claims that a generic drug is ineffective or unreasonably dangerous. "In the drug context, either increasing the 'usefulness' of a product or reducing its 'risk of danger' would require redesigning the drug: A drug's usefulness and its risk of danger are both direct results of its chemical design and, most saliently, its active ingredients." *Bartlett*, 133 S.Ct. at 2475. But "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based." *Id.* (citing 21 U.S.C. §§ 355(j)(2)(A)(ii)-(v) and (8)(B); 21 C.F.R. § 320.1(c)). Under *Bartlett*, a claim that a generic drug manufacturer's product is unfit for its intended use or unreasonably dangerous is one that would impose a duty to alter the composition of that drug. *See Bartlett*, 133 S.Ct. at 2474–75; *see also Bartoli v. APP Pharm., Inc.*, (*In re Pamidronate Prod. Liab. Litig.*), 842 F.Supp.2d 479, 485 (E.D.N.Y.2012) (a "breach of implied warranty claim necessarily alleges that defendants should have changed the design of [a drug] to make it safe and fit for its intended uses" and is therefore preempted (quotation omitted)); *In re Fosamax Prods. Liab. Litig*. (No. II), No. 08–008, 2011 WL 5903623, at *8 (D.N.J. Nov. 21, 2011) (unpublished) ("[B]reach of implied warranty claim necessarily alleges that manufacturers should have changed [a drug's] design. This would be in violation of the federal duty of sameness, and therefore, this claim is preempted.").

Id. at 1288–89. Accordingly, Plaintiff's claims related to defective design, premised on either strict liability or negligence are subject to preemption and are hereby dismissed.

Although Plaintiff contends he has pled a claim based on an alleged manufacturing defect, the Court concludes that Plaintiff's Amended Petition fails to state any such claim. Plaintiff does not allege therein that the azithromycin was not manufactured as would be anticipated. Rather, Plaintiff's claims stem from the alleged failure to warn of the dangerous risks posed by the prescription and the inherent danger of the medicine. Under Oklahoma law, "[a] product is defective in manufacture if it deviates in some material way

from its design or performance standards. The issue is whether the product was rendered unsafe by an error in the manufacturing process," which is "often established by showing that a product, as produced, failed to conform with the manufacturer's specifications." *Wheeler v. HO Sports, Inc*., 232 F.3d 754, 757 (10th Cir.2000)(internal quotation marks and citations omitted). Plaintiff makes no allegations that would give rise to such a claim, rather he contends that every dose of azithromycin was defective because of its design and/or lack of adequate warnings. As such, Defendant is entitled to dismissal of Plaintiff's manufacturing defect claim.

Plaintiff also seeks relief under a theory of negligence, alleging that Teva failed to adequately warn doctors and consumers of the dangers affiliated with azithromycin. In support of this argument Plaintiff cites to various cases where it was determined that claims were not preempted because the generic drug manufacturer failed to update its labeling in accordance with updates to the brand-name drug label. *See Teva Pharm. USA, Inc. v. Superior Cour*t, 217 Cal. App. 4th 96, 158 Cal. Rptr. 3d 150 (2013); *Boros v. Pfizer, Inc.*, 2016 WL 3131403 (Del. Super. Ct. 2016). Plaintiff argues that he alleges similar facts in this case, citing to paragraphs 87 and 88 of the Amended Petition. Those paragraphs provide:

> 87. Defendants made the representations and actively concealed information about the defects and dangers of Azithromycin with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Azithromycin as a treatment.
>
> 88. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials set forth above, Plaintiff ingested Azithromycin and suffered injuries as set forth herein.

Neither of these paragraphs provides Defendant Teva with notice that it is alleged to have failed to update its labeling on the ANDA to conform to the labeling of the reference listed drug Zithromax.[1] Accordingly, without regard to whether a negligent failure to update claim would be preempted, Plaintiff failed to sufficiently allege any claim that arguably could avoid preemption.

To the extent Plaintiff's negligence or strict liability claims are premised on the failure to provide additional warnings, such claims are preempted. There is no shortage of authority that outlines the legal requirement that a ANDA drug must have the same warnings as the reference listed drug. In *Mensing*, the Supreme Court held that the FDCA preempts any state law that requires companies to improve generic drug labels. 564 U.S. at 616–20, 131 S.Ct. 2567. The Court reasoned that it would be impossible for companies to change both the generic drug label and maintain sameness with the corresponding brand-name drug label. *Id.*

Plaintiff acknowledges *Mensing* but contends that 2007 amendments to the FDCA, known as the FDCAAA, should be applied and alter the outcome herein. The Court disagrees. The court in *In re Fosamax*, 2011 WL 5903623 (D. N.J. Nov. 21, 2011), examined the issue and rejected the same contention.

[1] The Amended Petition makes an entirely contrary allegation at paragraph 18, asserting that "Defendant Pfizer is responsible for Defendant Teva for its failure to provide adequate warnings which were repeated by Teva." The only reference to a label change is at paragraph 21 of the Amended Petition, wherein Plaintiff alleges "Additionally, Defendants failed to disseminate a 'Dear Doctor' letter to physicians concerning the label change or the risk of irreversible Stevens-Johnson syndrome." There are no allegations, however, regarding the specifics of "the label change" that Defendant failed to disseminate so as to support a claim that Defendant Teva failed to adhere to the sameness requirement for labeling the ANDA.

> Contrary to Plaintiffs' assertions, the Food and Drug Administration Amendments Act ("FDAAA") does not change this analysis. First, nothing in FDAAA alters *Mensing's* analysis of the viability of sending Dear Doctor Letters. Specifically, FDA regulations still require that letters be "consistent with and not contrary to such approved or permitted labeling." 21 C.F.R. 201.100(d)(1). Thus, Generic Defendants could not, without violating federal law, advise prescribing physicians of warning information different from that provided in the FDA-approved label. Second, FDAAA did not change the fact that the Generic Defendants still cannot unilaterally change their alendronate sodium labels. Under the amendments, once FDA "becomes aware of new safety information" that it "believes should be included in the labeling" of a drug, FDA must notify the reference-listed drug manufacturer. 21 U.S.C. § 355(o)(4)(A). Then the manufacturer must propose a change to the label reflecting the new safety information and the FDA must act upon this proposal. Id. § 355(a)(4)(B)-(C). Importantly, under this section, if the manufacturer of the branded drug is still marketing the drug, as is the case here, FDA must first approach that manufacturer. *Id.* § 355(a)(4)(A). Only if the branded drug is no longer being marketed can the FDA require a generic manufacturer to propose a change. *Id*. And even if the Generic Defendants were to notify FDA of "new safety information," there is no guarantee that the branded drug's labeling would ultimately be changed. *See id.* § 355(o)(4)(C). Accordingly, the *Mensing* analysis is not affected by FDAAA because the Generic Manufacturers are still unable to unilaterally change drug labeling "without special permission and assistance, which is dependent on the exercise of judgment by a federal agency." *Mensing*, 131 S.Ct. at 2581.

Id. at *7.

The Seventh Circuit recently addressed the issue in *Wagner v. Teva Pharm. USA, Inc.*, 840 F.3d 355 (2016).

> Wagner claims that *Mensing* and *Bartlett* are outdated in light of the FDAAA, which the Supreme Court did not consider. Other courts have rejected this argument. E.g., *In re Fosamax* (*Alendronate Sodium) Prod. Liab. Litig. (No. II)*, No. CIV. 08–008 GEB–LHG, 2011 WL 5903623, at *7 (D.N.J. Nov. 21, 2011); *Whitener v. PLIVA, Inc.,* No. CIV.A. 10–1552, 2011 WL 6056546, at *3 (E.D. La. Dec. 6, 2011) (*citing In re Fosamax*). We reject it as well, as we did in *Houston v. United States*, 638 Fed.Appx. 508, 513–514 (7th Cir. 2016). The FDAAA imposed certain obligations on generic drug manufacturers when they propose labeling changes. But the FDAAA did not remove the prohibition against doing so unilaterally. As we noted in

> *Houston*, "the amendments still forbid a generic-drug maker from violating the duty of sameness without FDA permission." I*d.* at 514.

Id. at 359. This conclusion is underscored by the pending FDA proposed rule, Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 FR 67985. The proposal has been pending since 2013 and was designed to respond to the Supreme Court authority of *Mensing and Bartlett.* If implemented the rule would permit the sponsor of a generic drug to issue a labeling change using an FDA CBE-0 application for safety-related changes, which would start a process intended to permit differences between the labeling of that drug, the reference listed drug and any other approved ANDA on a temporary basis. The proposed rule would be unnecessary if, as Plaintiff urges, the 2007 Amendments permitted unilateral labeling changes by generic manufacturers. As such, dismissal of Plaintiff's strict liability, product's liability and negligence claims based on Defendant's alleged failure to warn is appropriate.

Plaintiff seeks relief under theories that Defendant Teva breached both express and implied warranties. The Tenth Circuit addressed warranty claims in *Schrock* and concluded that such claims were preempted.

> Our analysis of whether the [Plaintiff's] state law warranty claims are preempted thus "begin[s] by identifying [Qualitest's] duties under state law." [*Bartlett*, 133 S.Ct.] at 2473. Under Oklahoma law, an express warranty is defined as "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain," "[a]ny description of the goods which is made part of the basis of the bargain," or "[a]ny sample or model which is made part of the basis of the bargain." Okla. Stat. tit. 12A, § 2–313(1)(a)–(c). Unless excluded or modified, a warranty that goods are "merchantable is implied in a contract

> for their sale if the seller is a merchant with respect to goods of that kind." Okla. Stat. tit. 12A, § 2–314(1). To comply with this warranty, goods must:
>
> > (a) pass without objection in the trade under the contract description; and
> > (b) in the case of fungible goods, [be] of fair average quality within the description; and
> > (c) [be] fit for the ordinary purposes for which such goods are used; and
> > (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
> > (e) [be] adequately contained, packaged, and labeled as the agreement may require; and
> > (f) conform to the promises or affirmations of fact made on the container or label if any.
>
> § 2–314(2)(a)–(f).

727 F.3d at 1287-88. Plaintiff herein alleges that Defendant represented that azithromycin was safe, but that it was not safe and had an increased risk of side effects. Similarly, with regard to his implied warranty claim, Plaintiff alleges that the medication was not of merchantable quality or safe and fit for its intended usage. In *Schrock*, the Tenth Circuit concluded that implied and express breach of warranty claims premised on the lack of warning or the adequacy of the warning and labels are preempted. The court noted the "sameness" requirement for both the composition and labeling of generic drugs and the FDA's broad definition of "labeling."

> No effort is made to identify a mechanism through which Qualitest could have modified or supplemented the warranties allegedly breached without running afoul of the duty of sameness identified in *Mensing*. Accordingly, the Schrocks' claims are preempted to the extent they rest on inadequate labeling as broadly defined by the FDA.

Id. at 1288. The same holds true for Plaintiff Kious's breach of warranty claims based on failure to provide adequate labels and warnings. Furthermore, to the extent Plaintiff

contends the product was not merchantable, and therefore breached an implied warranty, *Schrock* instructs that such claim is preempted.

> Under Oklahoma law, products are "merchantable" or "fit" if they "operate for their ordinary purpose." *Perry v. Lawson Ford Tractor Co*., 613 P.2d 458, 463 (Okla.1980). We conclude that these claims, based on allegations of dangerousness or ineffectiveness, are also preempted because Qualitest could not have altered the composition of the metoclopramide it manufactured without violating federal law. In *Bartlett* the Supreme Court held that the reasoning of *Mensing* extends to "warning-based design-defect cause[s] of action" asserted against generic manufacturers. *Bartlett*, 133 S.Ct. at 2477. The Court noted that under the state law at issue, a manufacturer has a duty to "ensure that the products they design, manufacture, and sell are not unreasonably dangerous," which can be "satisfied either by changing a drug's design or by changing its labeling." *Id*. at 2474. As in *Mensing*, the Court explained that labeling changes are preempted because generic manufacturers have a "federal-law duty not to alter [a drug's] label." *Bartlett*, 133 S.Ct. at 2473.

Id. at 1288.

Similarly, the Court finds that Plaintiff's claims of fraud, negligent misrepresentation and negligent concealment are preempted. As aptly stated by the Eleventh Circuit Court of Appeals in *Guarino v. Wyeth*, 719 F.3d 1245 (11th Cir.2013),

> Guarino's attempt to elude *Mensing* by clothing her allegations as "failure-to-communicate" claims rather than failure-to-warn claims does not alter our analysis. No matter the garb in which she attempts to present them, Guarino's claims are at bottom allegations regarding Teva's failure to warn her of the dangers of long-term metoclopramide use, and they therefore cannot escape *Mensing's* grasp.

Id. at 1249, *see also In re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Products Liability Litigation*, 2015 WL 7272766 (S.D.Ill. 2015)("[P]laintiff's fraud, negligence, and misrepresentation claims . . . are premised on misrepresentations or inadequacies in [defendant's] labeling,

promotions, and advertisements. As such, Teva could only avoid liability as to these claims by unilaterally strengthening their warning labels in violation of federal law or by leaving the marketplace altogether. *Mensing* and *Bartlett* establish that such challenges to [defendant's] labeling are preempted."); see also *Lashley v, Pfizer*, 750 F.3d at 474–75 & n. 7 (5th Cir. 2014) (applying preemption holding to claims under Texas law and stating that "[r]egardless of the specific form in which the argument is styled (negligence, fraud, deceptive trade practices), each charge is, at base, a failure-to-warn claim.").

Having considered the parties' submissions, the Court concurs with Defendant Teva that Plaintiff's claims are preempted by the provisions of the FDCA that mandate "sameness" with regard to an ANDA drug and is reference listed drug counterpart with regard to both the composition of the drug and the labeling thereof. As such, Defendant is entitled to dismissal of Plaintiff's Complaint and its Motion to Dismiss (Doc No. 9) is therefore granted. To the extent Plaintiff believes he attempted to plead a claim that Defendant Teva's label deviated from that of the reference listed drug during the relevant time frame, the Amended Petition fails to sufficiently allege facts to support such a claim.

IT IS SO ORDERED this 8th day of December, 2016.

DAVID L. RUSSELL
UNITED STATES DISTRICT JUDGE